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#### III. REMARKS

Applicants respectfully request reconsideration of this application in view of the following remarks.

# 1. Status of the Claims

Claims 64-68 are pending in this application. No amendments to the claims have been made in this response and therefore, Claims 64-68 remain pending for examination on the merits.

# 2. Restriction Requirement/Election of Species

Claims 64-68 have been restricted under 35 U.S.C. §121 to the inventions defined by the Examiner in the Office Action. For the following reasons, Applicants respectfully traverse this requirement for restriction.

The Examiner has indicated that Claims 64-68 allegedly contain a large number of separate and distinct inventions. Specifically, the Examiner has indicated that each definition of each variable X', Z, Y', m, Y", R', R" and n forms a separate and distinct invention.

In response, Applicants first respectfully point out that the presently claimed invention is directed to a method of preparing a library of compounds using the specifically defined method steps (a), (b), (c) and (d). Accordingly, any prior art relevant to the present invention will probably relate to methods of generating compound libraries and not necessarily to particular compounds. Thus, if the Examiner were to focus his search on the claimed invention, i.e., the particular steps used to generate a library of compounds, the Examiner should be able to conduct the search without undue burden.

More importantly, by concluding that each definition for each variable X', Z, Y', m, Y'', R', R'' and n forms a separate and distinct invention, the Examiner is improperly dissecting Applicants' invention into a multitude of inventions conceived of only by the Examiner and not by the inventors. Such dissection of the members of a Markush group is improper according to the courts and the MPEP.

More specifically, in In re Weber, Soder and Boksay, the court stated:

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As a general proposition, an applicant has a right to have *each* claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not affect the right of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification. *In re Weber, Soder, and Boksay*, 580, F.2d 455, 458-459, 198 U.S.P.Q. 328, 331-332 (C.C.P.A. 1978) (emphasis in original).

Additionally, according to MPEP §803.02, "[s]ince the decisions in *In re Weber*...and *In re Haas*..., it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." In the present case, the Examiner has not made, nor has he even attempted to make, a proper showing that the present claims lack unity of invention. Accordingly, the present restriction requirement is improper and should be withdrawn.

While a restriction requirement is improper, according to MPEP §803.02, the Examiner may properly require a <u>provisional</u> election of species prior to examination on the merits for a Markush group where the members of the Markush group are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the claim obvious under 35 U.S.C. §103 with respect to the other member(s). However, it is important to note that this provisional election of species is <u>not a restriction requirement</u> and, according to the MPEP, each claim is to be examined fully with respect to the elected species and further to the extent necessary to determine patentability for the entire claim. See MPEP §803.02.

For the foregoing reasons, the requirement for restriction of Claims 64-68 is clearly improper. Accordingly, Applicants respectfully request that this restriction requirement be withdrawn and that the present claims be examined in their full scope according to the procedures set forth in the MPEP using the election of species information set forth below.

### 3. Election of Invention

Although traversing the restriction requirement for the above reasons, to comply with 37 C.F.R. 1.143, Applicants hereby elect the invention defined by selecting the following variables for the group:

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$$-X'-Z-(Y'-Z)_m-Y''-Z-X'-$$

m is 0; each X' is -C(O)-; each Z is alkylene; and Y" is a covalent bond.

By selecting these variables, a group of the following formula is formed:

-C(O)-alkylene-alkylene-C(O)-.

# 4. Election of Species (Compound Species)

The Examiner has further indicated that an election of a single disclosed species is allegedly required under 35 U.S.C. §121. Specifically, the Examiner has indicated that Applicants are required to elect a single disclosed species having a specific ligand and a specific linker.

In order to comply with this election of species requirement, Applicants hereby elect the following compound having a specifically defined ligand and a specifically defined linker:

$$\begin{array}{c|c} & & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & &$$

This compound is specifically disclosed in Example A8 on page 135 of the application.

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The Examiner has also requested a listing of all claims reading on the elected species. In this regard, Applicants again remind the Examiner that the present invention is directed to a method of preparing a library of compounds - not particular compounds. Accordingly, none of the pending claims read on this compound per se. However, the methods of Claims 64-68 read on methods in which such a compound is generated as part of a library of compounds using the claimed methods.

#### 4. Election of Species (Ligand and Linker Species)

The Examiner has also indicated that Claim 64 is allegedly generic to a plurality of disclosed patentably distinct species comprising (i) reactive functional groups on the ligand compound, wherein the reactive functional group is selected from the group consisting of -NH<sub>2</sub>, -COOH, -C(O)Y, -CHO, -OH, -SH, -N=C=O and -Y, where Y is halo; and (ii) two reactive functional groups in a linker compound independently selected from the group consisting of -NH2, -COOH, -C(O)Y, -CHO, -OH, -SH, -N=C=O and -Y, where Y is halo. Accordingly, the Examiner has indicated that Applicants are required to elect a single disclosed species for a specific ligand compound and a specific linker compound.

In response, Applicants elect the following species:

**Ligand Compound** 

$$H_2N$$
 $NH_2$ 
 $NH_2$ 

In the elected species, the reactive functional group on the ligand compounds is -NH<sub>2</sub>; and the reactive functional group on the linker compound is -COOH. These ligand and linker compounds are specifically disclosed in Example A8 on page 135 of the application.

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## 5. Information Disclosure Statement

An Information Disclosure Statement (IDS) was submitted to the USPTO on April 30, 2002, for the above-identified patent application. Consideration of the documents submitted in this IDS and return of an Examiner-initialed copy of the form PTO/1449 with the next Office Action is respectfully requested.

#### 6. Conclusion

Reconsideration of this application in view of the above remarks and early examination on the merits is respectfully requested. Should the Examiner have any questions regarding this paper or should any issues arise that can be resolved by telephone, the Examiner is encouraged to telephone the undersigned attorney for Applicants at (650) 808-6406.

Respectfully submitted, THERAVANCE, INC.

Date: August 17, 2004

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Telephone No. (650) 808-6406

THERAVANCE, INC. 901 Gateway Boulevard South San Francisco, CA 94080 Phone: (650) 808-6000

Fax: (650)-808-6078